UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,247	01/25/2002	Ethan Lerner	10287-066001 / 1791.1	2777

26161 7590 12/17/2003

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	10

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/057,247	Applicant(s) LERNER ET AL.	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-11 and 18-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The indicated allowability of claims 6, 12 and 19 is withdrawn in view of the newly discovered reference(s) to Lerner et al. (WO 98/33379), Zucchetti et al. (U.S.Patent No. 6,037,481) and Yamaguchi et al. (EP 0755671A1). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al. (WO 98/33379) in view of Zucchetti et al. (U.S.Patent No. 6,037,481).

Lerner et al. teach a topical composition comprising Applicants' NOS inhibitor (e.g. L-NAME) for the treatment of unwanted conditions of skin associated with aging in a subject (a human). (abstract, page 2, lines 16-17, page 9, line 34, page 11, lines 26-38, page 13, lines 26-38, page 7, lines 25-29).

Lerner et al. do not expressly teach the treatment of wrinkle or fine wrinkle, the composition as being sterile and the evaluating the effect of the wrinkles.

Zucchetti et al. teach that the wrinkles are unwanted effects of the skin aging.

It would have been obvious to one of ordinary skill in the art to modify the Lerner et al.'s method to treat wrinkles or any wrinkle conditions (e.g. fine wrinkles) because Learner et al. teach that composition comprising L-NAME is useful for the unwanted conditions of skin associated with aging and that wrinkles are the unwanted conditions of the skin aging as taught by Zucchetti et al. One would have been motivated to make such a modification in order to achieve expected benefit of reducing unwanted aging conditions of skin (e.g. wrinkles) as taught by Lerner et al. as modified by Zucchetti et

al. Absent any evidence to contrary, there would have been a reasonable expectation of successfully treating skin wrinkles with L-NAME. To provide a sterile composition, and the evaluating the effect of medication to determine prognoses (by evaluating the effect of wrinkles) of the disease condition are all deemed obvious since they are all within the knowledge of the skilled artisan and represent conventional technique to manufacturing formulations to avoid contaminants and the routine performance of the physician to treat patients.

Claims 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al. as applied to claims 1, 3-5, 7 and 9-11 above, and further in view of Yamaguchi et al. (EP 0755671A1).

Lerner et al. as applied as before and additional teachings as follow:
Lerner et al. teach that L-NAME is useful for the treatment of sunburn or other exposure to ultra-violet light. (page 4, lines 1-5,page 9, lines 33-35, page 11, line 26-page 12, line 4).

Lerner et al. do not expressly teach the treatment of wrinkles caused by exposure to UVB radiation.

Yamaguchi et al. disclose that it has been known that the formation of wrinkles is accelerated by exposure to ultraviolet rays, UV-B. (page 2, lines 23-25).

It would have been obvious to one of ordinary skill in the art to employ L-NAME for the treatment of wrinkles caused by ultra-violet light, UV-B because Learner teach the treatment of unwanted epidermal or dermal conditions comprising exposure to ultra-

violet light and wrinkles are the conditions caused by ultra-violet light, UV-B as well-known by Yamaguchi et al. One would have been motivated to make such a modification to achieve expected benefit of treating a disorder caused by exposure to ultra-violet light (e.g. wrinkles) as generally taught by Lerner et al. Absent any evidence to contrary, there would have been a reasonable expectation of successfully treating wrinkles caused by exposure to ultra-violet light, UV-B with L-NAME to a patient suffering from wrinkles by exposure to ultra-violet light.

Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al. (WO 98/33379) in view of Zucchetti et al. (U.S.Patent No. 6,037,481) as applied to claims 1, 3-5, 7 and 9-11 above, and further in view of Remington's Pharmaceutical Sciences, 17th Edition.

The teachings of Lerner et al. and Zucchetti et al. as applied as before and additional teachings of Lerner et al as follows.

Learner et al. teach that the composition comprising L-NAME can be combined with a non-toxic dermaologically acceptable vehicle or carrier as a cosmetic composition. (page 14, lines 23-29).

Either reference does not teach the instructions for the using the composition to prevent wrinkles.

Remington's Pharmaceutical Sciences teaches that there is an increased awareness that labeling instructions are frequently inadequate to ensure patient understanding of his medication and his adherence or compliance with recommended

instruction and that the responsibility that the patient receive specific instructions precautions, and warnings for safe and effective use of prescribed drugs is the shared responsibility of the prescriber and the pharmacist. (page 1792, under Patient Counseling Information).

It would have been obvious to one of ordinary skill in the art to include the instruction for using composition to reduce wrinkles and the directions to apply to the skin prior to sun exposure in Learner et al's composition because Learner's composition is effective for unwanted skin condition associated with aging such as wrinkles and the conditions (wrinkles) caused by exposure to ultraviolet light as taught by Learner as modified by Zuccetti et al. and because there is an increased awareness that labeling instructions are frequently inadequate to ensure patient understanding of his medication and his adherence or compliance with recommended instructions. One would have been motivated to include an instruction with Learner's composition to fulfill the responsibility that the patient receive specific instructions precautions, and warnings for safe and effective use of prescribed drugs as the prescriber and the pharmacist.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

12/15/03

Jmk
December 8, 2003